Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University

SESSION: PLANNING/MONITORING SIG BREAK-OUT

Session Information	**Date: May 30, 2007** **Time: 1:30 p.m.–3:10 p.m. PDT** **Presenter/Lead: CTMS Lead: John Speakman** **DSIC Lead: Elaine Brock** **Facilitator: Diane Rickman** **Scribe: Susan Varghese**
Executive Summary	The session began with an overview of the Planning/ Monitoring Special Interest Group (SIG), including its goals and its various projects. Considerable discussion centered on scope validation of the projects and applications that fall under the purview of this SIG. The various projects and tools include Study Initiation Tool (SIT), Division of Cancer Prevention (DCP) Enterprise System Knowledgebase, Protocol Lifecycle Tracking System, Investigator and Site Credential Repository, and FIREBIRD. Identifying the clinical trial business process was seen as a key activity that will need to occur so that the functionalities of the various tools can be mapped more clearly. Requirements for some of these tools were identified. Existing tools at various institutions or commercial systems should be investigated to determine whether one of these systems could be adapted to meet the planning/ monitoring requirements of the National Cancer Institute (NCI) community. Various Data Sharing and Intellectual Capital (DSIC) policies relevant to data sharing based on the current scoping of these tools were conducted.
Discussion	• John Speakman presented an overview of the Planning/ Monitoring SIG, including its goal and its various projects. His presentation is available at https://cabig.nci.nih.gov/workspaces/CTMS/CTMS_Face_to_Face_Meetings • The goal of the SIG is to facilitate the *planning* and instantiation of clinical trials (and their *monitoring* of trials once they are instantiated). • The various projects and applications that fall under this SIG are— 1. SIT 2. DCP Enterprise System Knowledgebase (DESK) 3. Protocol Lifecycle Tracking (PLT) 4. Investigator and Site Credential Repository (ISCR) 5. FIREBIRD. • The SIG discussed each of the applications in detail either to identify the scope and/or validate the scope. **Study Initiation Tool** • SIT, a tool that was recommended by the Clinical Trials Working Group (CTWG), is an NCI initiative. According to the CTWG Report,[1] the SIT would be a web-based trial initiation portal to facilitate Phase III treatment and complex Phase II protocol activation at sites. The functionality will be similar to the trial initiation materials provided to sites by industry sponsors and will include a checklist that reminds sites of staff and services that must be in place to successfully implement a trial (e.g., personnel

[1] http://integratedtrials.nci.nih.gov/ict/CTWG_report_June2005.pdf

requirements, necessary infrastructure, Institutional Review Board (IRB) submission requirements, data management needs, procedure instructions, etc.).

- The target users of the SIT must be identified: cancer centers, smaller institutions or both?
- The functionality requirements of the Tool (the "what") must be identified, not the implementation aspects (the "how").
- The desired functionalities of SIT that should be considered include—
  - A "checklist" functionality, although this functionality is one of the features that would either interface with other systems from sponsors and trial sites or be integrated into the local CTMS systems so that the status of the trial initiation process and missing documents and approvals, etc, could be identified
  - Data sharing, informed consent process, and trial resource list
  - Capability to act as a complete electronic replacement for paper
  - Ability to be interoperable with other systems, including the Clinical Trial Database
  - Ability to support investigator-initiated trials
  - Scope of SIT in terms of clinical trial phases and types of trials (drug trials/device trials/both)
  - Support for Phase II and III. The CTWG report lists Phase II and III but should SIT be limited to just those? Are there specific requirements in initiating different phases of trials? The Cancer Therapy Evaluation Program (CTEP) and DCP will need to be consulted to clarify. Also, because the demarcations between phases are becoming less distinct (example: now there are Phase 0/I, Phase I/II), would it be better to include all phases of trials?
  - Dependency on other applications. Identify dependencies between SIT and other applications—could FIREBIRD feed the SIT checklist?
- Other SIT-like tools should be identified to discover other potentially desirable functional behaviors.
- The scope of SIT will be better addressed when the project is established and a Vision and Scope document is developed and vetted with the community. This document will address the components of the clinical trials process that the SIT will encompass.
- One approach regarding the clinical trials process that was suggested is to leverage Pharma and Biotech process, distill aspects of the process that are essential and relevant and then synthesize the requirements. Once a list of requirements is developed, it can be validated with CTEP and DCP.

DCP Enterprise System Knowledgebase

- DESK is a set of web-enabled systems to support the scientific and administrative work of the NCI DCP. DESK is also a way to standardize data across clinical trials and distribute information to DCP and its contractors.
- DESK includes a DCP internal database that tracks a protocol from submission to approval. It covers the entire lifecycle of a study and a protocol document.

Protocol Lifecycle Tracking

- The PLT tool will assist in managing and documenting a protocol through the entire lifecycle of the trial, starting at Concept Development and continuing through to the end of the cycle with Submissions and Publications.
- Various storyboards presented would enable different stakeholders to use the PLT system to track a protocol through its lifecycle.
  - Investigators could model workflows and develop a configurable decision tree for protocol development.

  - Institutional leadership could use the PLT system as a high-level dashboard to view the status of pending and approved protocols.

- PLT should be built so that it will be user friendly and capable of capturing exceptions.
- This system must be very granular in terms of the data that will be included.
- Investigation of existing systems that may provide this functionality should be considered (e.g., Velos was suggested by the University of Michigan).

Investigator and Site Credentials Repository

- The ISCR will be a credentialing system for clinical trial investigators and sites that is recognized and accepted by NCI, industry sponsors, clinical investigators, and clinical trial sites.
- This system will be a credentials repository, rather than a system that will credential investigators or sites.
- Existing systems to be potentially considered as the basis of such a system include FIREBIRD and the Clinical Trial Support Unit's Regulatory Support System (RSS). FIREBIRD currently submits credentials (Form 1572) to the Food and Drug Administration (FDA); RSS supports the IRB process but is not set up to interoperate with DESK.
- It can be envisioned that the ISCP (credential repository) will feed into FIREBIRD (for submission to FDA).

FIREBIRD

- FIREBIRD (Federal Investigator Registry of Biomedical Information Research Data) automates the Form 1572 registration process, a key activity in the regulatory data submission process and compliance requirements for investigators participating in clinical trials.
- A consideration for FIREBIRD would be to add the functionality of submission of investigator and site documents for trials that do not require Form 1572 (e.g., medical devices trials).

DSIC Policies Relevant to Planning/ Monitoring Tools

- Elaine Brock from the DSIC Workspace facilitated the discussion on what data sharing policies are applicable to the tools under the Planning / Monitoring SIG.
- Discussion on what data sharing policies are applicable to the tools under the Planning/Monitoring SIG centered on Intellectual Property (IP) value, data sensitivity, IRB restrictions, and sponsor restrictions. The policies were categorized as high, medium, and low impact based on the DSIC Decision Tree for Privacy/ Intellectual Capital Terms and Conditions.
- For purposes of this discussion, it was decided that FIREBIRD functionalities overlap with those of ISCR, and DESK functionality overlaps with that of PLT, so the DSIC considerations are generally equivalent.

The various policies relevant to each of the tools were identified and are available in the detailed Planning/ Monitoring SIG Report-Out presentation located with the materials from the May 2007 CTMS Face-to-Face Meeting on the caBIG website.

Requirements

Requirement ID	Description
PM 1	SIT will support all clinical trial activities until "open to accrual."
PM 2	PLT will manage and document a protocol through the entire lifecycle of the trial, starting at Concept Development and continuing through to the end of the cycle with Submissions and Publications.

Issues

Identifying the clinical trial business process was seen as a key activity that will that will then allow clearer mapping of the functionalities of the various tools.

Action Items

Assigned To	Description	Due Date
	☐ Review CTEP and DCP clinical trial business process to identify a common workflow. ☐ To identify the requirements for SIT, collect examples of check lists and other functionalities from Pharma/ Biotech, U.S. Army, Veterans Affairs, etc. ☐ Investigate institutions (University of Michigan, University of Dartmouth, University of New Mexico) that have systems that have functionalities required in PLT.	

Next Steps

1. Identify the business process for the entire clinical trial and map the various tools that support Planning/ Monitoring to specific activities. When identifying the sequence of the activities, specify which activities are in lock-step sequence, which are in parallel, and which can be out of sequence (or flip-flopped). The business process should include three levels—managing the study, managing the data, and managing participants.
2. Identify open source workflow tools that can be modified or adapted to meet the needs of the NCI community in planning and monitoring a trial.

Attendees

	Last Name	First Name	AFFILIATION
1.	Brock	Elaine	University of Michigan
2.	Budd	Troy	NCI/Division of Cancer Prevention
3.	Collyar	Deborah	Patient Advocates In Research (PAIR)
4.	Courtney	Paul	Dartmouth/Norris Cotton Cancer Center
5.	Fridsma	Doug	University of Pittsburgh
6.	Friedman	Steven	Cancer Therapy Evaluation Program, NCI
7.	Jones	Dennie	University of New Mexico Cancer Research and Treatment Center
8.	Joyce	Niland	City of Hope National Medical Center
9.	Kaefer	Christine	NCI Center for Bioinformatics

11.	Rickman	Diane	Booz Allen Hamilton
12.	Speakman	John	NCI Center for Bioinformatics
13.	Varghese	Susan	Booz Allen Hamilton